Patient-Reported Outcomes version of the CTCAE (PRO-CTCAE)

Overview

This page and its subpages contain presentations, agendas, and documents pertinent to the PRO-CTCAE initiative to develop a patient-reported outcomes version of the NCI's Common Terminology Criteria for Adverse Events (CTCAE).

Presently, in NCI-sponsored treatment trials, adverse events are documented using items from the CTCAE. The CTCAE is a lexicon of approximately 1000 discrete items (>1000 in v3 and <1000 in v4), representing laboratory tests, measurable phenomena (like temperature or blood pressure), and symptoms. Each item is graded with up to five ordinal response options, with each response option anchored to discrete clinical criteria (which may include information about severity, frequency, and/or interference with daily activities). By design, CTCAE items elicit the worst magnitude of a phenomenon being measured.

Currently, all CTCAE items are reported by research staff at clinic visits, including adverse symptoms. Patient self-reporting does not play a role. But evidence suggests that clinical staff systematically underreport symptoms compared to patients' own accounts. A further recognized limitation of the current approach is that adverse symptoms are only reported by staff at visits and not between visits, with up to several weeks elapsing between reporting instances. Since the recall period for the CTCAE represents the entire period since the prior clinic visit, symptom information may be lost due to degradation of memory about intervening events.

To address limitations of the current model, in October 2008 the NCI issued a contract to develop a patient-reported outcomes (PRO) version of the CTCAE. This contract was awarded to Memorial Sloan-Kettering Cancer Center with Dr. Ethan Basch as Principal Investigator. The Program Officer is Dr. Bryce Reeve of the NCI Health Outcomes Branch. Dr. Basch established a consortium of subcontractor cancer centers with site investigators at each providing content expertise applicable to the overall initiative. This includes Dana-Farber (Drs. Deborah Schrag and Vish Viswanath); Mayo Clinic (Drs. Jeff Sloan and Amylou Dueck); MD Anderson (Drs. Charlie Cleeland and Tito Mendoza); Duke University (Dr. Amy Abernethy); University of Pennsylvania (Drs. Deb Bruner and Laura Hanisch); and Memorial Sloan-Kettering (Drs. Jennifer Hay and Thomas Atkinson). Dr. Andy Trotti serves as a consultant. A subcontract with SemanticBits LLC as technology developer was also established. Key participants from across NCI divisions and FDA were also included, as well as patient advocate representatives (see below roster).

The RFP and SOW for the initial announcement, as well as sections of the response are posted as attachments to this page. Briefly, the overall scope of the initiative was divided into 9 discrete Tasks, with a site investigator designated as team leader for each. Each of these nine Tasks became a working group with independent schedules of meetings/teleconferences to provide its deliverables according to a coordinated schedule for the overall project. Each Task has its own subpage on this Wiki site to which pertinent documents are posted.

The Tasks include:

Task 1: To create a White Paper outlining barriers and strategies for widespread implementation of the PRO-CTCAE in NCI cooperative groups.

Task 2: To identify items in the CTCAE amenable to patient self-reporting, and create patient versions of these items. This task also includes determining the structure of PRO-CTCAE items and response options.

Task 3: To account for issues of cultural/health literacy and respondent diversity throughout the project.

Task 4: To conduct cognitive interviews for items developed in Task 2.

Task 5: To create a web-based open-source technology platform for administration of items in clinical trials.

Task 6: To conduct usability testing to refine the technology platform created in Task 5.

Task 7: To conduct a multicenter study of the measurement properties of the newly developed PRO-CTCAE items, including validity, reliability, sensitivity, and appropriate recall period.

Task 8: To design multicenter feasibility studies of the PRO-CTCAE in the NCI cooperative group setting.

Task 9: To create print and electronic training/educational materials for the PRO-CTCAE overall system (web platform and questionnaires).

Task 10: To translate the PRO-CTCAE into Spanish for increased accessibility.

The overall mission of the PRO-CTCAE initiative is to "Employ rigorous scientific methods to create a system for patient self-reporting of adverse symptoms in cancer trials, which is widely accepted and used; generates useful data for investigators, regulators, clinicians and patients; and is compatible with existing adverse event reporting systems." For further information about the PRO-CTCAE or to become involved, please contact the PRO-CTCAE project manager, Laura Sit: sitl@mskcc.org.

Conference calls for all tasks are recorded and are accessible to the public on Gforge.

Meetings

Please see individual Task subpages for details of meetings and teleconferences, or contact Laura Sit at sitl@mskcc.org.

Task Teams

The PRO-CTCAE project divided into several task teams, each focused on a specific component of the overall project. Below are the tasks and the prinicples for each task team.

- Project Manager:
  Laura Sit (sitl@mskcc.org)
- Finance Contacts:
  Roxana Damian (damianr@mskcc.org)
  Brendan Phalan (phalanb@mskcc.org)

- Task 1: Create "white paper" report
  (Bruner, Trotti, Schrag)
- Task 2: Develop PRO-CTCAE items
  (Cleeland, Sloan, Mendoza, Viswanath, Hay, Atkinson, Burke, Georghegan)
- Task 3: Assure cultural literacy
  (Vishwanath)
- Task 4: Cognitive interviewing
  (Hay, Shiman, Atkinson, Viswanath)
- Task 5: Build technology platform
  (Chilukuri and SemanticBits team, Shouery)
- Task 6: Usability testing
  (Abernethy)
- Task 7: Assess measurement properties (validation study)
  (Sloan, Cleeland, Mendoza)
- Task 8: Feasibility studies in cooperative group setting
  (Schrag, Bruner, Abernethy)
- Task 9: Create training/educational materials
  (Vishwanath/Kaiser)

Non-Disclosure Agreement (NDA) and Personnel List

All investigators and their staff on the personnel list must complete and return a non-disclosure agreement to MSKCC by Thursday October 30th.

The witness listed for the NDA should be the site investigator or another PI for the contract at your site. A faxed or scanned copy is acceptable by the date above, but please then drop a signed copy in the mail to me at the address below.

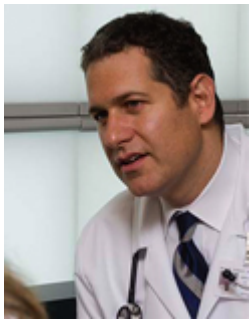
If necessary, please respond and update the personnel list to include all staff members at your institution that will be involved in the contract and/or will have access to the contract data/information.

Questions? - Please contact Brendan Phalan (phalanb@mskcc.org) or Laura Sit (sitl@mskcc.org).

Security Awareness Courses

All staff must also complete the Entire Computer Security Awareness Course (http://irtsectraining.nih.gov) by Thursday, October 30th, and return a completion certificate to MSKCC. Please login as "general public."
Questions? - Please contact Brendan Phalan (phalanb@mskcc.org) or Laura Sit (sitl@mskcc.org).

Project Team

	Personnel	Admin	Committee(s)
	Ethan Basch *PI*, MSKCC basche@mskcc.org 646-735-8154	Laura Sit *Project Manager*, MSKCC sitl@mskcc.org 646-735-8146	(All)
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	Bryce Reeve *Project Officer*, NCI (DCCPS) reeveb@mail.nih.gov 301-594-6574		(All)
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	Diana Paul *Patient Advocate*		
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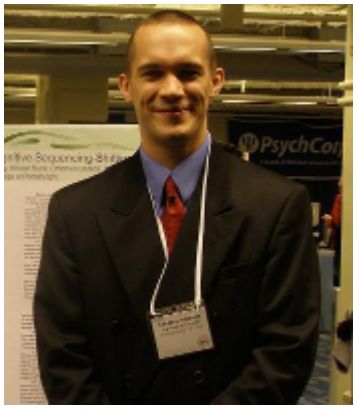	Thomas Atkinson *Psychometrician*, MSKCC atkinsot@mskcc.org 646-735-8132		Task 1: "White paper" Task 2: Items development Task 4: Cognitive interviewing Task 7: Validation study

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